Title: Holder for radioactive substances.

The invention relates to a holder for radioactive substances, especially for liquid radioactive pharmaceuticals.

Radioactive substances, such as pharmaceuticals are presently packaged within a glass container, normally referred to as vial, which is surrounded by a lead shielding. An absorbent material is placed between the vial and the shielding, after which the vial and shielding are positioned within an air and fluid tight tin. Such package is a legal and tested method for packaging radioactive liquids, normally preventing leakage of said substance and increase of radiation to the environment.

When this known package is handled inappropriately, for example when it is dropped the glass vial can break, which will result in contamination of the absorbent material with the radioactive liquid. Consequently, the level of radioactivity outside the package may then increase significantly. Furthermore, such package is relatively difficult to handle and costly, especially since a tin has to be used for air and liquid tight sealing of said package.

It has been proposed to use a plastic inner container in order to avoid breakage. However, a glass vial is preferred since it has superior properties for contacting different kinds of radioactive substances without the risk of contamination to said substances and physical or chemical reactions between said vial and said substances. Moreover, glass vials are relatively easy to clean, for example by sterilisation.

A main object of the present invention is to provide for a holder for radioactive substances in which the drawbacks of the known holders as discussed hereabove are avoided, maintaining the advantages thereof. This main object is reached according to the present invention by providing for a holder having the features of claim 1.

In a holder according to the present invention the first container is air sealed and liquid tight, which first container contains the radioactive substance. Said first container is then enclosed within an air and liquid tight second container, which second container is essentially unbreakable. The thus gas and liquid tight first and second containers are enclosed within shielding means preventing leakage of radiation to the environment.

When the first container, for example a glass vial, is damaged, for example by inappropriate handling of the holder, the radioactive substance cannot reach the shielding means since the substance will be contained within the essentially unbreakable second container. Since this second container is gas and liquid tight, said substance cannot leave said second container. Thus the shielding means do not necessarily have to be air and liquid tight, nor do these shielding means have to be contained within a further air and liquid tight containing means such as a tin known from the prior art.

Since the first and second liquid and air tight containers are provided within the shielding means, a holder according to the present invention is very safe and easy to use, relatively small with respect to the inner dimensions of the first container and relatively economical in use. Especially when the first container is made of glass and the second container is made of a relatively clear plastic material, the substance contained within the first container can be visually checked from the outside of the second container without the necessity of opening said second container, whereas the advantages of glass are provided for.

In an advantageous embodiment a holder according to the present invention is further characterized by the features of claim 2.

By providing for a third container in which the first and second container can be enclosed, said third container providing for the shielding means, a holder according to the

present invention is even more practical in use. The first and second container can be withdrawn from said third container, for example for visual inspection of the substance contained therein or for assessment of the radioactivity of said substance. Thus the radioactivity can be measured without the necessity of removal of the first container from the second container depending on the type of radiation. This has the major advantage that even during handling of the first and second containers without said shielding the danger of leakage of the substance to the environment is sufficiently prevented by said second container. Therefore, all necessary inspections of the substance are possible without the necessity of direct contact with the first container or the substance.

In a first preferred embodiment a holder according to the present invention is characterized by the features of claim 4.

The combination of a glass first container, a plastic second container and a metal third container provides for the combination of a relatively inert vial in direct contact with the contained substance, an easy to handle, essentially unbreakable second container and a good shielding means. Especially lead is advantageous for the shielding means.

Instead of use of a third container the second container itself can be provided with or provide for the shielding means. For example, the second container can be provided with a layer of lead or similar shielding material or, when the radiation is of an alpha- or beta-type, the second container can be made of an appropriate plastic material such as PVC, polycarbonate or the like plastic material absorbing or reflecting alpha- or beta-type radiation. However, a third container, essentially providing for the shielding means is preferred since it is then possible to measure the radiation of the substance through said first and second containers.

In a further advantageous embodiment a holder according to the present invention is characterized by the features of claim 5.

By providing for a septum in the first and second container, which septa during use overlay each other at least partly, a needle can be introduced into the first container, without the necessity of removal of said first container from said second container. Thus at least part of the substance can then be removed from or a further substance can be introduced into said first container directly, preventing contamination of and leakage from said first container to the environment.

In a further elaboration of the present invention a holder is further characterized by the features of claim 7.

By providing for a stop or the like in the shielding means the first and second septa can be penetrated or otherwise engaged after removal of said stop without the necessity of complete removal of the shielding means. This further reduces the risk of radiation to the environment, which could be hazardous, for example to humans, animals, plants or products.

In a second preferred embodiment a holder according to the present invention is further characterized by the features of claim 8.

Such holder has the advantage that, if necessary, the lid of the second container can be removed or repositioned without the necessity of removal of said first and second containers from the third container and without the necessity of manual engagement of said lid, said second container or even the third container. This has the important advantage that the risk of contamination of for example an operator is even further reduced without impairment of the functionality of the holder.

At least the first and second container are preferably made of a material suitable for use in an

autoclave or other sterilisation means. This provides for the possibility of easy cleaning of said containers.

The invention further relates to a set or a holder according to the present invention and an instrument for engagement of said holder, characterized by the features of claim 12.

The present invention further relates to the use of a holder or a set according to the present invention, characterized by the features of claim 13.

Measurement of the radiation of the substance through the first and second container has the advantage that the risk of contamination of the environment by the radioactive substance is significantly reduced.

The present invention further relates to the use of a holder or set, characterized by the features of claim 14.

The invention further relates to a method for shielding a radioactive substance, characterized by the steps according to claim 15.

Such method provides for the possibility of easy handling of a radioactive substance without the risk of contamination of the environment by said substance and without the risk of an allowable increase of radiation to the environment. Furthermore, this method provides for a holder containing a radioactive substance which is easy to handle, for example in storage, transport and treatment, suitable for use with all kinds of radioactive substances, which is very safe and economical. Moreover, such method and holder can be easily used in normal, existing production environments, hospitals and the like.

Further advantageous embodiments of a holder, use or method according to the present invention are described in the sub claims.

In order to further elucidate the present invention, embodiments of a holder and method according to the present invention are described hereafter, with reference to the drawings. These show:

Fig. 1 partially in sectional view a first and second container, in assembled position;

fig. 2 a second container in opened position in top and side view;

fig. 3 a first and second container, in assembled position, enclosed within a third container;

fig. 4 partly in sectional side view part of an assembly as shown in figures 1-3, together with an instrument for opening, closing and manipulating the second container; and

fig. 5A and 5B the assembly as shown in figure 4 in sectional view along the line V-V, before and during engagement of a second container.

fig. 6 a first and second container, in assembled position enclosed within a third container in an alternative embodiment;

fig. 7a-c a dispensing assembly according to the present invention;

fig. 8a-b an alternative embodiment of an instrument for opening, closing and manipulating the first and second container;

fig. 9 an instrument according to fig. 8, manipulating a second container; and

fig. 10 the instrument according to fig. 8, manipulating the first container.

Figure 1 shows in side view a first container 1, enclosed within a second container 2. The first container is made of glass and is somewhat bottle or vial shaped, having a lid 4 provided with a piercable first septum 6, shown in dotted lines. The container or vial 1 is intended for containing radio-active substances. The glass is inert to such substances. The lid 4 closes the first container 1 liquid and air tight. The glass of the first container 1 is preferably clear, such that a substance contained therein can be visually inspected, although the glass may also be made partly or completely opaque.

The second container 2 comprises a container body 8, a second septum 10 and a second lid 12. As shown in figure 1 the second septum 10 can be clamped between the upper edge 14 of the container body 8 and the inner top surface 16 of the second lid 12, in order to close said second container liquid and air tight. An opening 18 is provided in said top surface 16, such that the second septum 10 is engagable from the outside through said opening 18. The second lid 12 is provided with inner thread 20, cooperating with outer thread 22 on the container body. The second lid 12 is provided with a circumferential wall 24 on top of the top surface of the lid 12, in which wall notches 26 are provided for example two positioned opposite each other, the use of which will be explained later. The outer dimensions of the first container 1 are preferably such that it can fit snugly into the container body 8, such that when the second container 2 is closed the second septum 10 lies at a relatively short distance from the top of the first lid 4 of the first container 1. The second septum 10 thus lies at a short distance from the first septum 6, such that a needle (not shown) can pierce the first 6 and second septum 10 in order to penetrate the first container 1 for introduction of fluid into or withdrawal of liquid from said first container without the risk of contamination. Once tightly closed, the second container 2 encloses the first container 1 liquid and air tight.

The second container is made of a plastic material, preferably a clear plastic material, such that the first container 1 and even the substance contained therein can be visually inspected through said second container 2. The plastic material used for the second container is for example polycarbonate or a similar material which can for example be sterilized in an autoclave at a temperature of for example 120°C. The second container 2 preferably has a relatively thin wall, minimizing the risk of interference during measurement of for example radio activity of a substance

contained in the first container. Moreover, the overall size of the second container can thus be minimized.

When the radioactive substance contained in the first container radiates only alpha or beta type radiation, the second container can be made of a non-scattering plastic material absorbing or reflecting alpha or beta type radiation, such as PVC, polycarbonate or the like, wherein the second container itself provides for shielding means. However, as shown in figures 3 and 4, preferably a third container 30 is used, in which the first and second containers 1, 2 can be enclosed. In the embodiment shown in figure 3, the first and second containers 1, 2 are made cylindrical, the first and second septum 6, 10 respectively being clamped under the relevant lid 4, 12, such that the first and second septum 6, 10 are piercable by the same needle through opening 18. The third container 30 is made of a shielding material, impenetrable by alfa, gamma or beta type radiation. The third container is preferably made of lead or a different suitable shielding material, depending on the type of radiation. The second container fits relatively snugly into the third container, whereby the third container 30 is provided with a third lid 32, which can close the third container. The third lid 32 is provided with a central opening 34, closed by a lead stopper 36. When the stopper 36 has been removed the opening 18 and the underlying septa 6, 10 of a first and second container 1, 2 can be engaged, for example by said needle, without the necessity of completely removing the third lid 32. Thus the risk of leakage of radiation to the environment is even further reduced. The third lid 32 can be fixed onto the wall 38 of the third container 30, for example by bayonet screw threader snap fitted thereon.

A radioactive substance can be easily, economically and savely shipped in a holder according to the present invention, since leakage of said radioactive substance to the environment is prevented effectively. Should the first

container 1 break or otherwise leak, the radioactive substance will be retained within the plastic second container in a liquid and air tight manner. Thus, even if the second container is removed from the shielding means, for example said third container 30, the risk of contamination of the environment is prevented.

Direct contact between the first and/or second container 1, 2 and an operator or even close proximity should, where possible, be prevented. To this end, an instrument 40 has been provided for, as shown in figure 4. This instrument 40 comprises a relatively long, cylindrical handle 42, through which a central shaft 44 extends coaxially. The shaft 44 is at one end provided with a grip 46, engaging the first end 48 of the handle 42, whereas the shaft 44 is provided at the opposite side with a substantially rectangular or oval spreading element 50, securely connected to said shaft 44. The handle 42 is at the second end provided with a slit 52, whereas the spreading element 50 is positioned between the two parts 54 positioned on either side of said slit 52. Both parts 54 are at their free end provided, on the outside, with a stub 56, extending approximately perpendicular to the longitudinal axis L of the shaft 44. By rotation of the shaft 44 and thus the spreading element 50 over an angle of approximately 90°, relative to the handle 42 and by means of the grip 46, as shown in figure 5B, the halves 54 and thus the stubs 56 are forced outward. The stubs 56 are positioned and dimensioned such that these can be inserted into the notches 26 of the circumferential wall 24 of the second lid 12, as shown in figure 5B. In this position the instrument 40 securely engages the lid 12, such that the second container 2 and the first container 1 contained therein can be manipulated by the instrument 40, for example taken out of or positioned in the third container 30. Therefore, the first and second containers 1, 2 can be transferred from the third container 30 to for example a radiation measuring unit or an infuser or the like, without

an operator having to physically engage said containers. Moreover, the lid 12 can be rotated by means of the instrument 40, in order to unscrew the lid from the container body 8 or to screw said lid 12 onto said container body 8, for example when the vial 1 has to be positioned in or taken out of the second container 2. To this end the second container 2 is provided near the bottom thereof with a number of outwardly protruding fins 58, whereas the third container 30 is provided with a preferably corresponding number of fins 60 in the wall 38, parallel to the longitudinal axis A of said third container. When the second container 2 is positioned into the third container 30, the fins 38 slide in between the fins 60. Thus, rotation of the second container 2 relative to the third container 30 is prevented by cooperating fins 58 and fins 60. Therefore, the container body 8 will be retained by the third container 30 when the instrument 40 is rotated around the longitudinal axis L thereof, providing for the possibility of positioning or removing of the lid 12. The instrument can be disengaged from the second container 2 by rotation of the spreading element 50 back to the position as shown in figure 5A, whereby the halves 54 are forced inward by their resilience, disengaging the stubs 56 from the notches or openings 26.

Use of the instrument 40 has the advantage that distance is provided between the person handling said instrument 40 and the first 1 and/or second container 2 and thus the source of radiation.

A holder according to the present invention can for example be used as follows.

A radioactive substance, for example a medicine, is positioned into the first container 1, which is then closed by the first lid 4. Then the first container 1 is positioned into the second container 2, which is then closed in a liquid and air tight manner, using the second lid 12 and the second septum 10. The lid 12 is screwed on using for example an instrument 40 as shown in figure 4. Without disengaging said

instrument 40 the second and first containers 2, 1 are lifted and positioned inside the third container 30, providing for shielding means. The instrument 40 is then removed, after which the lid 32 is positioned on the third container 30, thus completely shielding the first and second container to the environment. The holder is then ready for storage and transportation in a safe and economical manner.

In a hospital or the like the first and second container 1, 2 can be removed from the shielding means 30 after removal of the lid 32, using an instrument 40, for example for measurement of the radiation of the substance contained in the first container 1, without removal of the first container from the second container 2. When only (part of) the substance has to be withdrawn from the first container 1 an appropriate needle can be inserted through the first and second septum 6, 10, after removal of the stopper 36 from the opening 34 in the lid 32, leaving said lid 32 on the third container 30. This has the advantage that the radioactive substance can be withdrawn with minimal risk of radiation to the environment.

Fig. 6 shows in cross section an assembly according to the present invention, in an alternative embodiment, comprising a first and second container 1, 2, enclosed within a third container 130 comparable to a container 30 according to fig. 3, having an outer wall 138 having a width which is relatively small compared to the wall 38 of the embodiment described before. The third container 130 is enclosed within an outer container part 170, closely fitting and enclosing the third container 130, which fourth, outer container 170 is made of a shielding material, suitable for protection against the radiation of the sample within the first container. The outer container 170 is for example made of lead. A handle 172, pivotable around an axis 173 is attached to the third container 130. Two stubs 174 are connected to the handle 172, which stubs can engage in slots 175 in the wall of the fourth container 170 and the lid 132 of the third container 138 when

the handle is in a horizontal position, as shown in fig. 7B (with respect to a dispensing device). In this position the third container 138 can not be moved relative to the fourth container 170, due to the locking engagement of said stubs 174 and slots 175, which have a substantially elbow shape. When the handle 172 is moved to the upward position, as shown in fig. 6, the stubs 174 can be moved vertically out of the slots 175, through their open to ends. Thus the third container 138 can be lifted out of the fourth container by means of the handle 172, and can be positioned in the means as shown in fig. 7. Fig. 6 thus shows the assembly in a transporting position, the environment being protected against radiation in a suitable and safe manner. The outer container 170 forms a storage and transporting means, the handle 172 both locking and carrying means.

Before use the first 1, second 2 and third container 130 are taken out of the outer container 170. To which end the handle 172 is moved upward to an upright position. The third container 130 can then be lifted out of the outer container 170 and can be positioned in for example an assembly 180 as shown in fig. 7, as discussed hereafter.

An assembly 180 according to fig. 7 comprises a foot plate 181, two parallel arms 182 extending upwardly therefrom. Between the free ends of the arms 182 a casing 183 is suspended on a pivot axis 184, said casing 183 being comparable to the outer container 170 and made of similar shielding material such as lead. As shown in fig. 7 a pin 185 extends through one of said arms 182 into a retaining hole 186, such that pivoting of said casing 183 around said axis 184 is prevented as long as said pin 185 is not retracted from said hole 186. The third casing 130 containing the first and second containers 1, 2, can be placed in the casing 183 in an upright position, the septa 6, 10 near said neck 188. The handle 172 is then pivoted to a position as shown in fig. 7B, enclosing the third container 130 in said casing 183, the casing 183 being provided with slots 175A comparable to the

slots 175 in the fourth container 170, having the same fonction. A needle 190 of the dispensing means 199 such as an infusion system can then be introduced into the first container through said septa 6, 10. The casing 183 with said containers 1, 2, 130 will then be pivoted around said axis 184 after retraction of said pin 185, over an angle of 180°, after which said pin 185 is repositioned in a further retaining hole 186a. In this position the contents of the first container 1 can be dispensed through said dispensing means 191 under the influence of gravity, whereas the environment is shielded by at least the third container 130 and the casing 183.

A transporting and storage assembly according to fig. 6 and dispensing assembly 180 according to fig. 7 has the advantage that the first, second and third containers can be transported and stored in a safe and convenient manner, whereas only the third container has to be handled when transferring the first and second container into the dispensing assembly 180 without the risk of contamination. This is very convenient to the person transferring said containers since this means a major reduction in weight and dimension. The outer container 170 can stay in position, for example in a transport box and can be re-used. Preferably, the outer form and dimensions of the third container 130 match the inner dimension and form of the outer container 170 and/or the casing 183 in such a manner that only containers of a certain type can be used therewith.

Fig. 8 shows an alternative embodiment of an instrument 140 for handling first 1 and second containers 2. This instrument 140 comprises a relatively long, cylindrical handle 142 through which a central shaft 144 extends coaxially. The shaft 144 is again at one end provided with a grip 146 and at the other end with a locking element 150 extending perpendicular to the shaft 144, which locking element 150 has a length approximately equal to the diameter of the handle 142 (fig. 8a). Two slits 152 are provided on

opposite sides in the outer wall 145 of the handle 142, which slits 152 are open to the lower end 143 of said handle 142. Two cut-outs 151 are provided in the side edges of said slits 152, opposite each other, positioned such that when the locking element 150 extends between said cut-outs the grip 146 abuts the upper end 147 of the handle 142. The locking element 150 has a diameter corresponding to the width of the slits 152. The cut-outs 151 are for example semi circular having a radius larger than the radius of the locking element 150. As can be understood from fig. 8a, when the grip 146 abuts said upper end 147, the part 154 of the handle 142 extending on opposite sides of the slits 152 can be moved toward each other, the cut-outs 151 enclosing the locking element 150. Near the lower end 143, stubs 156 are positioned on the outer side of the part 154, extending radially into opposite directions. Therefore, when the parts 154 of the handle 142 are moved towards each other as discussed here above, said subs 156 are moved inward, that is to a position closer to each other. In this position the instrument 140 can be introduced into the circumferential wall 24 of the lid 12 of the second container 2, after which the parts 154 can be released, such that the stubs 156 are forced into the notches or openings 26 in said circumferential wall. The shaft 144 can then be pulled upward by the grip 146, such that the locking element 150 is forced into the slits 152, preferably in abutment with the side edges thereof. In this position, as shown in fig. 9, the parts 154 are kept outward and retained in this position by said locking element 150. In this position the second container 2 can be manipulated with said instrument 140 without the risk of disengagement of said instrument 140 from said second container 2, at least from the lid thereof. In this position the lid 12 can be screwed on or from said second container, whereas said second container can also be manipulated. It will be clear that the instrument 140 can be released from the second container by pushing the shaft 144 and locking element 150 down, back to

the position as shown in fig. 8a, after which the parts 154 can be resiliently forced toward each other again in order to retract the instrument 140 from said lid 12.

On the lower end 143 of the parts 154 a rim 157 is provided, extending inward, which rim can be positioned under the lid 4 of the first container 1. In this position the first container 1 can be easily manipulated by the instrument 140. Once again, the length of the instrument 140 provides for further protection of a person handling the first and second containers.

It will be clear to a person skilled in the art that an instrument according to the present invention could be designed in several equivalent manners. For example, the length of the shaft 144 could be designed such that when the grip 146 abuts the upper end 147, the locking element 150 is positioned in the slits 152 below the cut-outs 151 and should be retracted in order to enable movement of the parts 154 toward each other.

The present invention is not limited to the embodiments shown and described with reference to the drawings. Many variations are possible within the scope of the present invention as defined in the claims.

For example the first container can be made of a different material inert to radioactive substances and sterilization equipment. Furthermore, the first, second and third containers can have a different shape or configuration, as long as the first container, closed air and liquid tight can be enclosed within said second container in an air and liquid tight manner, shielding means, preferably in the form of a third container being provided for containing said first and second containers. The shielding means can however also be provided for by the second container or by at least one appropriate layer on said second container. Before withdrawal of the substance from the first container 1 said first container 1 can be retracted from the second container 2, such that for example the first lid 4 can be removed, if

necessary or desired. However, in view of the risk of contamination by radiation a method as described here before is preferred. Furthermore, the instrument and the second lid can be designed in a different manner for engagement of the first with the latter. Moreover, other means can be provided for prevention of rotation of the second container relative to the third container, for example by using second and third containers having at least partly a non circular form. The holder or at least the first and/or second can be sterilized in an autoclave, the containers or at least the space between the first and second container being filled with water or the like. However, any appropriate means for cleaning the holder can be used. Spreading and locking of the instrument can be obtained in a different manner, for example by a conical element moving in axial direction or similar constructions. Absorption means can be provided for in the second container.

These and similar alternatives are considered to fall within the scope of the present invention.